



Strengthening Quality, Driving Compliance and Enhancing Validation in Pharma Manufacturing

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Overview of Quality, Compliance, and Validation

Quality Assurance Importance

Quality assurance ensures pharmaceutical products are consistent, safe, and meet industry standards.

Regulatory Compliance

Compliance with FDA, EMA, and other regulations is essential to maintain market authorization and consumer trust.

Validation Processes

Validation confirms systems and methods consistently produce results that meet predetermined specifications.

Technology and Innovation

Advanced technologies like AI are enhancing efficiency and accuracy in quality, compliance, and validation.

Why Patient-Centricity is Non-Negotiable

Patient Safety Priority

Every decision in pharmaceutical manufacturing prioritizes patient safety and well-being to uphold ethical responsibility.

Regulatory Compliance and Trust

Patient-centricity ensures compliance with regulations while building sustained trust in healthcare systems.

Cultural and Operational Integration

Embedding patient-first principles transforms corporate culture and operational roles into critical health contributions.

Moral Imperative in

Manufacturing
Patient-centricity changes compliance from obligation to moral imperative to improve lives through manufacturing.

Building Robust Quality Frameworks

Quality Management System

A structured QMS provides processes for documentation, audits, and corrective actions to strengthen compliance.

Continuous Staff Training

Ongoing training programs keep staff updated on regulations and best industry practices.

Risk-Based Monitoring

Risk-based monitoring identifies potential issues early to prevent escalation and ensure quality control.

Data-Driven Quality Control

Leveraging data analytics enables predictive quality control to anticipate deviations proactively.

Modern Approaches to Validation

Lifecycle Perspective

Validation is an ongoing process, emphasizing continuous monitoring throughout the manufacturing lifecycle.

Digital Tools and Traceability

Digital tools enhance documentation accuracy and traceability, reducing errors and improving transparency.

Real-Time Monitoring

Real-time monitoring systems enable immediate detection of anomalies and continuous verification of critical parameters.

Compliance and Automation

Compliance with global standards combined with automated workflows accelerates validation without sacrificing accuracy.

AI Strategies to Augment Traditional Efforts

Predictive Maintenance

AI-powered predictive maintenance improves equipment reliability and reduces production downtime.

AI Quality Inspections

AI-driven quality inspections, deviation writing, continued process verification minimize human error and speed defect detection for better product integrity.

Automated Compliance Checks

Automation streamlines regulatory documentation and reduces administrative workload.

Supply Chain Forecasting

AI enhances inventory management by predicting supply chain demands and preventing shortages.

Commitment to Innovation and Patient Safety

Balancing Tradition and Innovation

Pharmaceutical industry upholds 'Patient First' principles while adopting AI and digital technologies for enhanced practices.

Advanced Technologies Enhancing Efficiency

AI, IoT, and blockchain enable real-time monitoring, transparent supply chains, and improved operational performance.

Ensuring Patient Safety and Trust

Commitment to innovation aligns with patient safety goals, reinforcing trust with patients and regulators.

FDA Draft Guidance on AI in Pharma

- **Scope:** AI in drug development, clinical trials, pharmacovigilance, and manufacturing
- **Risk-Based Credibility Framework:** Evaluate models based on context of use
- **Transparency:** Disclose training data, algorithms, and decision processes
- **Lifecycle Management:** Continuous monitoring for data drift and performance
- **Manufacturing Implications:** Validation and reliability testing for AI-driven processes

Agentic Agents

- Move beyond generative AI to maximize benefits
- AI Agents allow us to truly treat the tool like an extension of our teams
- One idea- Can AI Agents can be treated like employees and trained rather than validated?
Validate data sources and transfer, but not the agent itself
- Our employees become reviewers and can focus on important tasks rather than data collation
- We cannot be afraid to find patterns and new challenges that present opportunities for improved patient safety and outcomes

Thank you
Q&A

